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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/571,466	08/25/2006	Thomas Rueckle	285616US0PCT	6605
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OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314				
EXAMINER				
WEDDINGTON, KEVIN E				
ART UNIT		PAPER NUMBER		
1614				
NOTIFICATION DATE		DELIVERY MODE		
09/15/2008		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/571,466

Applicant(s)

RUECKLE ET AL.

Examiner

Kevin E. Weddington

Art Unit

1614

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11, 22-25 and 40-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11, 22-25 and 40-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Claims 11, 22-25 and 40-43 are presented for examination.

Applicants' request for continued examination, amendment and response filed June 9, 2008 have been received and entered.

Accordingly, the rejections made under obviousness-type double patenting over claims 1-36 of copending Application No. 10/070,954; over claims 1-27 of copending Application No. 10/088,074; over claim 1 of copending Application No. 10/088,090; over claims 1-8 and 14 of copending Application 10/381,197; over claims 1-8 and 14 of copending Application No. 10/381,200; over claims 1-10, 12 and 16 of copending Application No. 10/381,655; and over claims 1-11 and 17 of copending Application No. 10/484,744 as set forth in the previous Office action dated April 29, 2008 at pages 2-3 are hereby withdrawn because of applicants' remarks.

Accordingly, the rejection made under 35 USC 102(b) as being anticipated by EP 1,088,821 A1 (AN) of PTO-1449, hereby known as Arkinstall and as evidence by Bennett et al., "Current Opinion in Pharmacology, Vol. 3, No. 4, pp. 420-425, 2003 (AS) of PTO-1449 as set forth in the previous Office action dated April 29, 2008 at pages 3-4 is hereby withdrawn because the Arkinstall reference does not the applicants' preferred compounds of claims 11 and 22.

Accordingly, the rejection made under 35 USC 103(a) as being obvious over EP 1,088,821 A1 (AN) of PTO-1449, hereby known as Arkinstall in view of Weber et al. (3,454,635) as set forth in the previous Office action dated April 29, 2008 at pages 4-5 is hereby withdrawn because the Arkinstall reference does not the applicants' preferred compounds of claims 11 and 22.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11, 22 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 1,193,268 A1, hereby known as Halazy et al. as evidence by Bennett et al., "JNK: A new therapeutic target for diabetes", Current Opinion in Pharmacology, Vol. 3, No. 4, pp. 420-425, 2003 (AS) of PTO-1449.

Halazy et al. teach pharmaceutically active sulfonamide derivatives (same as applicants' claims 11 and 22). Note the instant compounds are effective modulators (inhibitors) of the JNK pathway. Note on page 13, section [0088] shows the modes of administration of the instant derivatives such as oral, rectal, transdermal, subcutaneous, intravenous, intramuscular and intranasal. Note on page 36, lines 27 and 30 disclose the applicants' preferred compounds.

Bennett et al. teach the JNK pathways have a connection with insulin resistance and type II diabetes (see page 420, under JNK, TNF and insulin resistance). Also note page 422, column 1, second paragraph, states that the JNK pathway is a novel target for the treatment of diabetes and obesity. Finally, on page 423, column 2, first paragraph, states that JNK inhibitors have the potential to show long-term benefit in diabetes by protecting pancreatic islet cells from apoptosis, in turn, allowing increased insulin secretion and prevention of hyperglycemia.

Claims 11, 22 and 25 are not allowed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 23-25 and 40-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 1,193,268 A1, hereby known as Halazy et al. in view of Weber et al. (3,454,635).

Halazy et al. were discussed above supra for the use of sulfonamide derivatives of formula I to treat metabolic disorders mediated by insulin resistance by the inhibition of the JNK pathway (the JNK pathway is known to cause diabetes and obesity, See Bennett et al., Curr. Op. Pharm., 3(4), pp. 420-425).

The instant invention differs from the cited reference in that the cited reference does not teach the addition of the other supplementary drugs as set forth in claims 23, 24 and 40-42. However, the secondary reference, Weber et al., teaches benzenesulfonyl-urea compounds such as glyburide, are well-known anti-diabetic agents.

Clearly, one skilled in the art would have assumed the combination of two individual agents, well-known to treat diabetes, into a single composition would give an additive effect in the absence of evidence to the contrary.

Claims 23-25 and 40-43 are not allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin E. Weddington whose telephone number is (571)272-0587. The examiner can normally be reached on 12:30 pm-9:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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